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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Technology Center: 1600

Kropshofer et al.

Art Unit: 1643

Application No. 10/676,675, filed October 1, 2003  
(Case Docket 21412)

Examiner: Christopher H. Yaen

For: NOVEL MHC II ASSOCIATED PEPTIDES

**PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.144**  
**TO WITHDRAW EXAMINER'S RESTRICTION REQUIREMENT**

Nutley, New Jersey 07110  
August 2, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully petition the Director under 37 C.F.R. § 1.144 for withdrawal of the Restriction Requirement issued March 10, 2006 and kindly request that the Director direct the Examiner to combine and examine certain groups together which were improperly divided into separate groups (as described below).

This petition is proper and timely because: (1) the Restriction Requirement was traversed and reconsideration was requested in a response filed on April 4, 2006; (2) the Restriction Requirement was made final by the Examiner in an Office Action mailed July 20, 2006; and (3) the petition is being submitted before appeal and before a final action on or allowance of the claims in accordance with 37 C.F.R. § 1.144.

In accordance with 37 C.F.R. § 1.181, the following is a statement of the facts involved, points to be reviewed, argument, and action requested.

**FACTS INVOLVED**

The instant application, entitled “Novel MHC Associated Peptides” was filed on October 1, 2003 with 40 claims. The Examiner divided the claims into **56** groups as set forth below:

I. Claims 1-6 and 22-31, drawn in part to a peptide selected from the group consisting of SEQ ID Nos: 1-13, and 21, a pharmaceutical composition and a diagnostic marker classified in class 530, subclass 300. A single sequence was also required to be selected from SEQ ID Nos: 1-13 and 21 that (according to the Examiner) “should not be construed as an election of species.” Thus, primary Group I was further divided into 14 separate Groups.

II. Claims 7-9, drawn to an antibody reactive with the antigenic peptide of primary Group I, classified in class 530, subclass 350. A single sequence was also required to be selected from SEQ ID Nos: 1-13 and 21 for which the antibody reacts that (according to the Examiner) “should not be construed as an election of species.” Thus, primary Group II was further divided into 14 separate Groups.

III. Claims 10-21, drawn to a nucleic acid molecule encoding a peptide or polypeptide of primary Group I, host cells comprising said nucleic acid, vectors comprising said nucleic acid, and a method of producing the antigenic peptide of primary Group I, classified in class 536, subclass 23.1. A single sequence was also required to be selected from SEQ ID Nos: 1-13 and 21 that (according to the Examiner) “should not be construed as an election of species.” Thus, primary Group III was further divided into 14 separate Groups.

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IV. Claims 32-40, drawn to a method of treating cancer comprising stimulating the production of protective antibodies or immune positive CD4+ cells comprising the administration of the peptides of primary Group I, classified in class 514, subclass 2. A single sequence was also required to be selected from SEQ ID Nos: 1-13 and 21 that (according to the Examiner) “should not be construed as an election of species.” Thus, primary Group IV was further divided into 14 separate Groups.

Accordingly, in total, the Examiner restricted and divided the Application into 56 (14 x 4= 56) Groups to be filed as 56 separate divisional applications.

On April 4, 2006, the Applicants traversed the restriction requirement and provisionally elected primary Group I and SEQ ID No. 1. On July 20, 2006, an Office Action was issued wherein the Examiner made the Restriction Requirement final. The restriction requirement, the Applicants’ response to the restriction requirement, and the Office Action making the restriction requirement final can be found in the image file wrapper.

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**POINTS FOR REVIEW**

First, is there a serious burden on the Examiner to rejoin and examine SEQ ID NOS: 1-4 as one group; SEQ ID NOS: 5-6 as one group; SEQ ID NOS: 7-9 as one group; SEQ ID NO: 9 as one group; SEQ ID NOS: 10-11 as one group; SEQ ID NOS: 12-13 as one group; and SEQ ID NO: 21 as one group.

Second, are the antibodies of Group II inseparable from and linked to the antigenic peptides of Group I by linking claims so that the Examiner is required to examine both Groups I and II together as part of the elected invention.

Third, does the Director have the authority or discretion to restrict inventions that are not both “independent” and “distinct” under 35 U.S.C. § 121.

## ARGUMENT

### I. There Is No “Serious Burden” To Combine Certain SEQ ID NOS. Into One Group

Under MPEP § 803, if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine such claims on the merits, even though they include claims to independent or distinct inventions. MPEP § 808.02 further states:

[T]he examiner, in order to establish reasons for insisting upon restriction, must >explain why there would be a serious burden on the examiner if restriction is not required. Thus, the examiner must< show by appropriate explanation one of the following:

- (A) **Separate classification thereof:** This shows that each \*>invention< has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.
- (B) **A separate status in the art when they are classifiable together:** Even though they are classified together, each \*>invention< can be shown to have formed a separate subject for inventive effort when \*>the examiner can show< a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.
- (C) **A different field of search:** Where it is necessary to search for one of the \*>inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries<, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

**Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among >independent or< related inventions.** (Emphasis added).

**A. All The SEQ ID NOS. Are Classified Exactly The Same In Each Primary Group**

All the SEQ ID NOS. are classified exactly the same in each primary Group (Groups I-IV). For example, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group I are all classified in class 530, subclass 300. Likewise, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group II are all classified in class 530, subclass 350. Similarly, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group III are all classified in class 536, subclass 23.1. In addition, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group IV are all classified in class 514, subclass 2. Accordingly, it is clear (and the Examiner does not appear to dispute the fact) that all the SEQ ID NOS. in each primary Group (Groups I-IV) are classified exactly the same and not classified separately as required by MPEP § 808.02(A).

**B. There Is No Separate Status In The Art**

As stated under MPEP § 808.02(B), inventions “classified together can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status . . .” However, the Examiner has presented no evidence of separate inventive effort or separate status in the art for each and every SEQ ID NO., nor has the Examiner cited any patents asserted to be evidence of such separate status. The Examiner argues that each SEQ ID NO. (each peptide of SEQ ID NOS. 1-13 and 21) is non-overlapping and not coextensive with any other SEQ ID NO.; and that all 14 SEQ ID NOS. constitute a separate and distinct search. See July 20, 2006 Office Action at page 3. However, this is completely untrue.

For example, SEQ ID NOS: 2-4 overlap and completely fall within SEQ ID NO. 1. *See* Table 1 which shows that the peptide of SEQ ID NO. 1 is derived from the protein Vimentin and

consists of 16 amino acids located at position 202-217. SEQ ID NO. 2 is the same as SEQ ID NO. 1, minus the first amino acid (15 amino acids located at position 203-217). Similarly, SEQ ID NO. 3 is the same as SEQ ID NO. 1, minus the first and last amino acid (14 amino acids located at position 203-216). Likewise, SEQ ID NO. 4 is the same as SEQ ID NO. 1, minus the last two amino acids (14 amino acids located at position 202-215):

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
1	16	UKRV-Mel-15a	TLQSFRQDVVDNASLAR	202-217	Vimentin
2	15	UKRV-Mel-15a	LQSFRQDVVDNASLAR	203-217	Vimentin
3	14	UKRV-Mel-15a	LQSFRQDVVDNASLA	203-216	Vimentin
4	14	UKRV-Mel-15a	TLQSFRQDVVDNASL	202-215	Vimentin

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because SEQ ID NOS. 1-4 are so close in structure, the Examiner has not shown that SEQ ID NOS. 1-4 are each a separate subject of inventive effort. Accordingly, SEQ ID NOS: 1-4 should be grouped together.

Similarly, SEQ ID NO: 6 (17 amino acids located at position 167-183 of Vimentin) overlaps and completely falls within SEQ ID NO. 5 (18 amino acids located at position 166-183 of Vimentin). SEQ ID NO. 6 is the same as SEQ ID NO. 5, minus the first amino acid as shown below:

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SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
5	18	UKRV-Mel-20c	NDKARVEVERDNLAEDIM	166-183	Vimentin
6	17	UKRV-Mel-20c	DKARVEVERDNLAEDIM	167-183	Vimentin

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because SEQ ID NOS. 5 and 6 are so close in structure, the Examiner has not shown that SEQ ID NOS. 5 and 6 are each a separate subject of inventive effort. Accordingly, SEQ ID NOS: 5 and 6 should be grouped together.

Likewise, SEQ ID NO: 8 (15 amino acids located at position 172-186 of the protein eIF-4A1) overlaps and completely falls within SEQ ID NO. 7 (16 amino acids located at position 172-187 of the protein eIF-4A1). SEQ ID NO. 8 is the same as SEQ ID NO. 7, minus the last amino acid as shown below:

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
7	16	UKRV-Mel-20c	SPKYIKMFVLDEADEM	172-187	eIF-4A1
8	15	UKRV-Mel-20c	SPKYIKMFVLDEADE	172-186	eIF-4A1

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because SEQ ID NOS. 7 and 8 are so close in structure, the Examiner has not shown that SEQ ID NOS. 7 and 8 are each a separate subject of inventive effort. Accordingly, SEQ ID NOS: 7 and 8 should be grouped together.

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Similarly, SEQ ID NO: 11 (13 amino acids located at position 503-515 of the protein IFN-induc. p78) overlaps and completely falls within SEQ ID NO. 10 (14 amino acids located at position 503-516 of the protein IFN-induc. p78). SEQ ID NO. 11 is the same as SEQ ID NO. 10, minus the last amino acid as shown below:

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
10	14	UKRV-Mel-20c	KS KIEDIRAEQERE	503-516	IFN-induc. p78
11	13	UKRV-Mel-20c	KS KIEDIRAEQER	503-515	IFN-induc. p78

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because SEQ ID NOS. 10 and 11 are so close in structure, the Examiner has not shown that SEQ ID NOS. 10 and 11 are each a separate subject of inventive effort. Accordingly, SEQ ID NOS: 10 and 11 should be grouped together.

Likewise, SEQ ID NO: 13 (16 amino acids located at position 668-683 of the protein melanotransferrin) overlaps and completely falls within SEQ ID NO. 12 (17 amino acids located at position 668-684 of the protein melanotransferrin). SEQ ID NO. 13 is the same as SEQ ID NO. 12, minus the last amino acid as shown below:

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
12	17	Ma-Mel-18a	GQ DLL FK DAT VRA PVG	668-684	Melanotransferrin
13	16	Ma-Mel-18a	GQ DLL FK DAT VRA PV	668-683	Melanotransferrin

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because SEQ ID NOS. 12 and 13 are so close in structure, the Examiner has not shown that SEQ ID NOS. 12 and 13 are each a separate subject of inventive effort. Accordingly, SEQ ID NOS: 12 and 13 should be grouped together.

### **C. The Field of Search Is the Same**

The Applicants respectfully submit that the Examiner has not shown a separate field of search for each SEQ ID NO. from SEQ ID Nos: 1-13 and 21. The Examiner argues that each SEQ ID NO. (each peptide of SEQ ID NOS. 1-13 and 21) is non-overlapping and not coextensive with any other SEQ ID NO.; and that all 14 SEQ ID NOS. constitute a separate and distinct search. See July 20, 2006 Office Action at page 3. However, this is completely untrue. According to the specification on page 8, paragraph [0029]-[0030]:

The MHC class II associated novel antigenic peptides of the invention originate from the cytoskeletal protein vimentin (SEQ ID NOS. 1 to 6), the translation fraction eIF-4A1 (SEQ ID NOS. 7 to 9), the IFN- $\gamma$  inducible protein p78 (SEQ ID NOS. 10 and 11) and the iron-binding surface protein melanotransferrin (SEQ ID NOS. 12 and 13) and melanoma antigen recognized by T-cells 1 (MART-1, Melan-A protein; SEQ ID NO: 21).

Thus, it is clear from the specification that SEQ ID NOS: 1-6 originate from a single protein (vimentin); SEQ ID NOS: 7-9 originate from a single protein (eIF-4A1); SEQ ID NOS: 10-11 originate from a single protein (IFN-induc. p78); and SEQ ID NOS: 12-13 originate from a single protein (Melanotransferrin).

In addition, as stated above, SEQ ID NOS: 2-4 overlap and completely fall within SEQ ID NO. 1. See Table 1 which shows that the peptide of SEQ ID NO. 1 is derived from the protein Vimentin and consists of 16 amino acids located at position 202-217. SEQ ID NO. 2 is the same as

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SEQ ID NO. 1, minus the first amino acid (15 amino acids located at position 203-217). SEQ ID NO. 3 is the same as SEQ ID NO. 1, minus the first and last amino acid (14 amino acids located at position 203-216). SEQ ID NO. 4 is the same as SEQ ID NO. 1, minus the last two amino acids (14 amino acids located at position 202-215) as shown below:

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
1	16	UKRV-Mel-15a	TLQSFRQDVVDNASLAR	202-217	Vimentin
2	15	UKRV-Mel-15a	LQSFRQDVVDNASLAR	203-217	Vimentin
3	14	UKRV-Mel-15a	LQSFRQDVVDNASIA	203-216	Vimentin
4	14	UKRV-Mel-15a	TLQSFRQDVVDNASL	202-215	Vimentin

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because the sequences are so close in structure, SEQ ID NOS. 1-4 are not subject to a separate field of search. Accordingly, SEQ ID NOS: 1-4 should be grouped together.

Similarly, SEQ ID NO: 6 (17 amino acids located at position 167-183 of Vimentin) overlaps and completely falls within SEQ ID NO. 5 (18 amino acids located at position 166-183 of Vimentin). SEQ ID NO. 6 is the same as SEQ ID NO. 5, minus the first amino acid as shown below:

SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
5	18	UKRV-Mel-20c	NDKARVEVERDNLAEIDIM	166-183	Vimentin
6	17	UKRV-Mel-20c	DKARVEVERDNLAEIDIM	167-183	Vimentin

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<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because the sequences are so close in structure, SEQ ID NOS. 5 and 6 are not subject to a separate field of search. Accordingly, SEQ ID NOS: 5 and 6 should be grouped together.

Likewise, SEQ ID NO: 8 (15 amino acids located at position 172-186 of the protein eIF-4A1) overlaps and completely falls within SEQ ID NO. 7 (16 amino acids located at position 172-187 of the protein eIF-4A1). SEQ ID NO. 8 is the same as SEQ ID NO. 7, minus the last amino acid as shown below:

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SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
7	16	UKRV-Mel-20c	SPKYIKMFVLDEADEM	172-187	eIF-4A1
8	15	UKRV-Mel-20c	SPKYIKMFVLDEADE	172-186	eIF-4A1

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<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because the sequences are so close in structure, SEQ ID NOS. 7 and 8 are not subject to a separate field of search. Accordingly, SEQ ID NOS: 7 and 8 should be grouped together.

Similarly, SEQ ID NO: 11 (13 amino acids located at position 503-515 of the protein IFN-induc. p78) overlaps and completely falls within SEQ ID NO. 10 (14 amino acids located at position 503-516 of the protein IFN-induc. p78). SEQ ID NO. 11 is the same as SEQ ID NO. 10, minus the last amino acid as shown below:

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SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
10	14	UKRV-Mel-20c	KS <del>K</del> I <del>E</del> DIRAEQERE	503-516	IFN-induc. p78
11	13	UKRV-Mel-20c	KS <del>K</del> I <del>E</del> DIRAEQER	503-515	IFN-induc. p78

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

See Table 1 on page 44 of the specification. Thus, because the sequences are so close in structure, SEQ ID NOS. 10 and 11 are not subject to a separate field of search. Accordingly, SEQ ID NOS: 10 and 11 should be grouped together.

Likewise, SEQ ID NO: 13 (16 amino acids located at position 668-683 of the protein melanotransferrin) overlaps and completely falls within SEQ ID NO. 12 (17 amino acids located at position 668-684 of the protein melanotransferrin). SEQ ID NO. 13 is the same as SEQ ID NO. 12, minus the last amino acid as shown below:

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SEQ. ID No.	LENGTH	MELANOMA CELL <sup>a</sup>	SEQUENCE <sup>b</sup>	POSITION <sup>c</sup>	PROTEIN SOURCE
12	17	Ma-Mel-18a	GQD <del>L</del> L <del>F</del> KDATVRAVPVG	668-684	Melanotransferrin
13	16	Ma-Mel-18a	GQD <del>L</del> L <del>F</del> KDATVRAVPV	668-683	Melanotransferrin

<sup>a</sup> Name of the melanoma cell line used after necrotization for pulsing dendritic cells.

<sup>b</sup> Sequences of the melanoma cell-derived peptides in one-letter-code

<sup>c</sup> Position of the epitope within the protein sequence

*See Table 1 on page 44 of the specification. Thus, because the sequences are so close in structure, SEQ ID NOS. 12 and 13 are not subject to a separate field of search. Accordingly, SEQ ID NOS: 12 and 13 should be grouped together.*

## **II. The Peptides Of Group I Are Inseparable From The Antibodies Of Group II**

In addition, the antigenic peptides of Groups I should be combined with the antibodies of Group II because the claimed antibodies of Group II are inseparable from, linked, and defined by the antigenic peptides of Group I.

The antibodies of Group II are inseparable from Group I because such antibodies are defined by their reactivity (or functional ability to bind) to the corresponding antigenic peptides of Group I. Without the antigens of Group I the antibodies of Group II could not be made since the antigens of Group I are required to raise or produce the antibodies of Group II. Thus, the antibodies of Group II are defined by and inseparable from the antigens of Group I. The antigenic peptides of Group I and the antibodies of Group II (reactive with the antigenic peptides of Group I) are also linked by a common linking claim (claim 1). *See* the antibody claims of claims 7-9 which are all dependent on the antigenic peptide of claim 1.

Pursuant to MPEP § 809, such inseparable linked claims must be examined with and are considered part of the invention elected. MPEP § 809 states:

There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the otherwise divisible inventions.

\* \* \* \*

The linking claims must be examined with, and thus are considered part of the invention elected.

Therefore, pursuant to MPEP § 809, the linked peptides of Group I (which are inseparable from the antibodies of Group II) should be joined and examined together.

The Examiner argues that there are only two types of linking claims: (a) genus claims linking species claims and (b) subcombination claims linking plural combinations (none of which apply to this situation). *See* the July 20, 2006 Office Action at pages 3-4. However, the Examiner is completely wrong. MPEP § 809 states that species and subcombination claims are examples of the most common type of linking claims (not that they are the only two types of linking claims that exist):

The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims; and
- (B) subcombination claims linking plural combinations (MPEP §809, emphasis added).

Thus, the Examiner is completely wrong on this point. Linking claims are not limited to species and subcombination claims. Claim 1 of the present invention (covering antigenic peptides) is a linking claim which links claims 7-9 of the present invention (covering antibodies).

### **III. The Director Does Not Have The Authority Or Discretion To Restrict Inventions That Are Not Independent And Distinct Under 35 U.S.C. § 121**

The Director does not have the authority under 35 U.S.C. § 121 to restrict inventions that are not independent and distinct under 35 U.S.C. § 121:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. 35 U.S.C. § 121 (emphasis added).

In the present application, it is not clear that the Examiner has restricted the application to inventions that are both independent and distinct inventions. *See* the arguments noted above.

In addition, it is respectfully submitted that the USPTO has been interpreting the term “independent and distinct” under 35 U.S.C. § 121 inconsistently with the written language of the statute. With regard to this point, MPEP § 809.01 states:

“Independent,” of course means not dependent . . . . A large number of inventions between which, prior to the 1952 Act, division has been proper . . . . If section 121 of the 1952 Act were intended to direct the Director never to approve division between dependent inventions, the word “independent” would clearly have been used alone. If the Director has authority or discretion to restrict independent inventions only, then restriction would be improper as between dependent inventions . . . . Such was clearly not the intent of Congress. Nothing in the language of the statute and nothing in the hearings of the committees indicate any intent to change the substantive law on this subject. On the contrary, joinder of the term “distinct” with the term “independent”, indicates lack of such intent. The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, “distinct” inventions, even though dependent.

However, the Applicants respectfully disagree with this interpretation of the 35 U.S.C. § 121. Statutes should be interpreted by their plain and ordinary meaning. Justice Scalia of the U.S. Supreme Court explains that courts “interpret laws rather than reconstruct legislators’ intentions. Where the language of those laws is clear, we are not free to replace it with an unenacted legislative intent.” *INS v. Cardoza-Fonseca*, 480 U.S. 421, 452-53 (1987) (concurring).

Accordingly, 35 U.S.C. § 121 clearly states that only independent and distinct inventions can be restricted. As MPEP § 809.01 correctly suggests, the term “independent” does not include

dependent claims dependent on independent claims. Thus, according to the plain and ordinary meaning of the statute (35 U.S.C. § 121), no dependent claim should ever be restricted. In addition, the term “and distinct” adds an additional requirement- which is that only independent claims which are also “distinct” can be restricted. The use of the word “and” clearly indicates that the statute should be read in the conjunctive form (not disjunctive form- otherwise Congress would have used the term “or”). *See Pueblo of Santa Ana v. Kelly*, 932 F. Supp. 1284, 1292 (D. N. Mex. 1996) (use of the conjunctive “and” in a list means that all of the listed requirements must be satisfied).

At a minimum, regardless of whether the Director agrees or disagrees with the above interpretation of the term “independent and distinct,” the Applicants respectfully request that the Director review the Examiner’s restriction requirement (using the PTO’s so-called “second pair of eyes”) and direct the Examiner to rejoin and examine any Groups that the Director believes are not independent and distinct inventions under the Director’s interpretation of 35 U.S.C. § 121.

### III. Conclusion

There is no serious burden on the Examiner to rejoin and examine SEQ ID NOS: 1-4 as one group; SEQ ID NOS: 5-6 as one group; SEQ ID NOS: 7-9 as one group; SEQ ID NO: 9 as one group; SEQ ID NOS: 10-11 as one group; SEQ ID NOS: 12-13 as one group; and SEQ ID NO: 21 as one group.

In addition, the antibodies of Group II are inseparable from, defined by, and linked by the antigenic peptides of Group I (by claim 1- the linking claim) such that the Examiner should be required to examine both Groups I and II together as part of the elected invention pursuant to MPEP §809.

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Finally, the Applicants respectfully submit that the Director does not have the proper legal authority or discretion under 35 U.S.C. § 121 to restrict inventions that are not both independent and distinct.

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**ACTION REQUESTED**

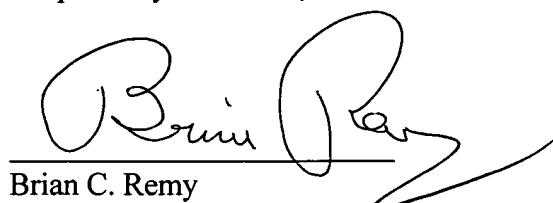
The Applicants respectfully request that the Director direct the Examiner to rejoin and examine SEQ ID NOS: 1-4 as one group; SEQ ID NOS: 5-6 as one group; SEQ ID NOS: 7-9 as one group; SEQ ID NO: 9 as one group; SEQ ID NOS: 10-11 as one group; SEQ ID NOS: 12-13 as one group; and SEQ ID NO: 21 as one group.

In addition, the Applicants respectfully request that the Director direct the Examiner to rejoin and examine the peptides (of Group I) together with the antibodies (of Group II).

Finally, the Applicants respectfully request that the Director review the Examiner's restriction requirement (using the PTO's so-called "second pair of eyes") and direct the Examiner to rejoin and examine any Groups that are not independent and distinct inventions.

It does not appear that there is any fee associated with the filing of this petition. However, the Director is hereby authorized to charge any deficit, or credit any overpayment, to Deposit Account No. 08-2525.

Respectfully submitted,



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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	10/676,675
		Filing Date	October 1, 2003
		First Named Inventor	Harald Kropshofer et al.
		Art Unit	1643
		Examiner Name	Christopher H. Yaen
Total Number of Pages in This Submission		Attorney Docket Number	21412

ENCLOSURES (Check all that apply)			
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):	Remarks <b>Petition To The Director Under 37 C.F.R. 1.144 To Withdrawn Examiner's Restriction Requirement</b>

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Brian C. Remy		
Signature			
Date	August 2, 2006		

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Brian C. Remy		
Signature			
	Date	August 2, 2006	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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